

8-11-99

Kimball

P.O. 40

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Cypress, TX

77410

Jane Henney, MD

Commissioner FDA

5600 Fishers Ln, Rm 1471

Rockville, MD 20857

Reference: FDA Approve Claims for Saw Palmetto

Comm. Henney MD

& Symptoms of benign
prostatic hyperplasia;
psyllium husk seeds &
heart disease; folic acid,
vit B6 & B12 & heart
disease; & vit E risk
for heart disease

Please approve the above
claims as outlined in attached.

Thank you

Kimball Family & Friends

99P-3029

C151

SPECIAL SUPPLEMENT

Julian Whitaker, M.D.

Health & Healing®

TOMORROW'S MEDICINE TODAY

Special Supplement to *Julian Whitaker, M.D. Health & Healing*
July 1999

A New Birth of Freedom for Supplement Health Claims



The United States Capitol served as the stage for this event.

May 25, 1999, was a blue-bird spring day. I was on the lawn in front of the nation's Capitol, along with Senators Orrin Hatch (R-Utah) and Tom Harkin (D-Iowa) and Congressman Peter DiFazio (D-Oregon). I had called a press conference to announce that I and three others had petitioned the Food and Drug

Administration (FDA) for "permission" to use truthful health claims on the labels of nutritional supplements. But before I get into our specific requests, you need to know why I was there at that time.

This Battle Started Eight Years Ago

For over 25 years the FDA has prevented nutritional supplement manufacturers from telling you about the health benefits of their products. Incredibly, billions of bottles of supplements have been sold *with no information at all* on the labels explaining what the product is supposed to do. Because the label is "off limits" as a source of information about nutritional and herbal products, consumers must turn to books, newsletters, and the Internet. But that is going to change—and change fast.

In January of this year, the Circuit Court of Appeals ruled that the FDA's 25-year-old regime of censorship of the nutritional supplement industry was both illegal and a violation of the constitutional guarantee of free speech and press. The court ordered the FDA to allow health claims that had been submitted eight years

ago by Durk Pearson and Sandy Shaw, long-time crusaders for freedom of speech on nutritional supplements, and which the FDA had categorically denied.

Now We're Filing Four Claims

At the press conference we announced the addition of four more claims that the FDA must act upon in the next six months. According to Jonathan Emord, the attorney who brilliantly and successfully argued this case before the courts, this will be the first real test of the FDA's willingness to adhere to the Court's decision—and act in the interests of confused consumers.

Let's take a look at the four specific claims we filed and how they might affect your health.



Julian Whitaker, pictured with Sen. Harkin, welcomed members of the press and made his opening remarks.

...plementary intake of folic acid, and vitamin B12 may reduce the risk of cardiovascular disease. An estimated 30% of all heart attacks could be prevented with supplemental folic acid, vitamin B6 and vitamin B12. Research in support of this statistic has existed for well over a decade. Because of the FDA's censorship of supplement manufacturers, many families who have lost a loved one to heart disease may understandably blame the FDA for their tragedy.

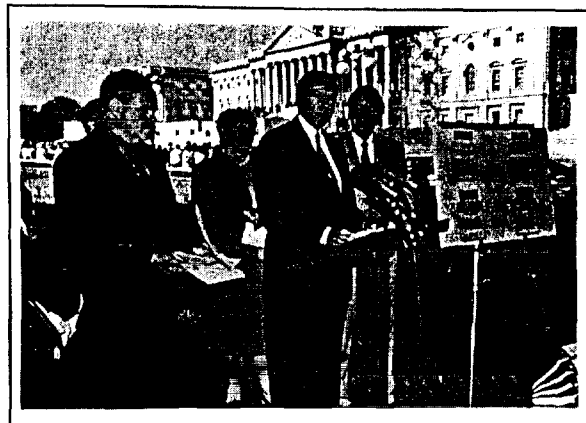
Claim 2. *Daily use of saw palmetto extract may improve urine flow and reduce nocturia and voiding urgency associated with mild benign prostatic hyperplasia (BPH).* BPH is such a common problem among men as they age that Representative DeFazio said in his statement to the press that this is the claim that might get the most attention from his colleagues in Congress, as they are "sitting around on their enlarged prostates." Studies show that supplemental saw palmetto results in significant improvements in the majority of men suffering with BPH.

Claim 3. *Psyllium seed husks used as a dietary fiber supplement may reduce the risk of heart disease.* Psyllium fiber has been shown to reduce total cholesterol and LDL cholesterol levels. Elevated levels of both affect 60% of American adults and are significant markers of heart disease.

Claim 4. *Supplemental vitamin E may help prevent cardiovascular disease.* The therapeutic potential and health benefits of vitamin E have been recognized for over 50 years, and the body of supporting scientific research continues to



With the distinguished panel standing behind him, Sen. Harkin urged the FDA to act in a prompt and timely manner.



Sen. Orrin Hatch chided the FDA for acting as the "nation's nanny."

grow. In one study of 2,000 people with heart disease, those taking supplemental vitamin E experienced a 75% reduction in heart attack incidence.

FDA Censorship Has Likely Harmed Many Americans

Folks, we need to remember that this issue directly affects people's lives. When a government agency is in violation of statutory law as well as the Constitution, the result is almost always disastrous for certain segments of the population. The FDA's censorship of vital information on the specific benefits of nutritional supplements is nothing short of perverse, and many years of suppression have caused immeasurable suffering, countless deaths, and billions of dollars in preventable medical costs. Let me give you one graphic example.

As long ago as 1992, there was substantial scientific evidence to show that 400 mcg of folic acid per day could reduce the risk of neural tube birth defects, such as *spina bifida* and *hydrocephalus*, by as much as 50%. In fact, the Center for Disease Control and Prevention (CDC) published the following recommendation that year:

"All women of childbearing age in the United States who are capable of becoming pregnant should consume .4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with *spina bifida* or other neural tube defects."

...role in making decisions for
...and that is a good thing. Seniors
...specially will derive tremendous benefits from
the nutritional information we now expect to
appear on the labels of nutritional supplements.

The Public Needs Accurate Information

Harry G. Preuss, MD, Professor of Medicine at Georgetown University Medical Center and a member of the Council for the Office of Alternative Medicine, gave a medical perspective of the situation. "...the public should be given proper information concerning the potential benefits of these nutraceuticals. There are other natural elements which could fall into this classification. Are there unforeseen possibilities for adverse reactions with long-term use? There is always a possibility. However, because of their natural status and long-term use, this is far more unlikely than the majority of 'cutting edge' pharmaceuticals now on the drug store shelves."

You Have a Right to Truthful Information on Nutritional Supplements

The impunity with which governments can transgress human freedoms is precisely why we have a constitutional government. The Bill of Rights was written not to protect you from dishonest nutritional supplement retailers, but to protect you from the forces of government. The first amendment to the Constitution says that government shall make no law to abridge freedom of speech. Yet the FDA instituted regulations that completely shut down speech on the value of nutritional supplements. Consequently, many intelligent people in our society still believe the nonsense that you can get all the nutrients you need for optimal health from diet alone. This is not to say that diet is an unimportant factor in health, but that the truth about the power of nutritional supplements has been rigidly and severely censored by the Food and Drug Administration.

Law Applies to Government Agencies, Too

When individuals in the private sector break the law and violate others' constitutional rights, they are punished. When individuals cloaked in the mantle of "government bureaucrat" break the law, violate others' constitutional rights and

cause immeasurable damage in the lives of millions, they merely get some bad press. All of that is beginning to change, however, and I'll keep you informed as to the progress of our petition through the bureaucratic labyrinth of the FDA.

Here's How You Can Help

Folks, you can play a part in this, too. Please write to:

Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 1471
Rockville, MD 20857

State that you are in favor of the FDA promptly approving claims filed for saw palmetto and the symptoms of benign prostatic hyperplasia; psyllium husk seeds and the risk of heart disease; folic acid, vitamin B6 and vitamin B12 and cardiovascular disease; and vitamin E and the risk of cardiovascular disease.

Please mail a copy of your letter to me, care of:

Health & Healing
Health Claims
7811 Montrose Road
Potomac, MD 20854

We're Winning, but We Must Stay Vigilant

The final court of appeals is the Supreme Court, but it is unlikely that the General Accounting Office will allow the FDA to spend taxpayers' money on yet another appeal to the courts, because their chances of having this decision reversed are so unlikely. This is why all of us are fighting to turn the FDA around completely, and at this junction we certainly are winning.

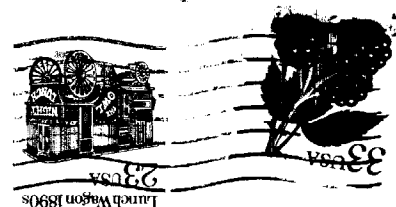
Julian Whitaker MD

CROSS FILE SHEET

File Number: 99P-3029/C151

See File Number: 99P-3030/C151

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